REMARKS:

Claims 1-10 are in the case and are presented for reconsideration.

1. Claims 1-10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wilhoit (US Patent 5,573,801, Col. 8) in view of Millis et al. (US Patent 5,286,506, Abstract). The basis of this rejection is that "[i]t would have been obvious to substitute hop beta acids for the bacteriacin used in Wilhoit since hop beta acids used alone are known to protect processed meat products, e.g. hot dogs, against Listeria contamination, as evidenced by Millis et al." (November 20, 2007 Office Action, paragraph 6).

It is respectfully submitted that while Millis et al. disclose that hop beta acids alone may successfully protect culture media against Listeria contamination; Millis et al. do not disclose that there acids alone may successfully protect meat products against Listeria contamination.[1]

Indeed, investigators in the field have recognized that Millis et al. did not disclose that hop beta acids may successfully protect meat products against Listeria contamination. Thus, for example, A. E. Larson et al. investigated Millis et al.'s proposal that hop components would be effective to protect foods from Listeria and they concluded that higher levels of hop components would be required to be effective in foods and that such "higher levels could impact desirable flavors and aroma characteristics to the food." International Journal of Food Microbiology, 33 (1996) 195 - 207, a copy of which is

[1] Millis et al. note that among the foods most likely to be contaminated with Listeria are meat products, (col. 3, lines 26 - 29), but that they do not state that the use of hop beta acids alone will successfully protect meat products against Listeria contamination.

enclosed. So, too, WO 01/06877 of King et al. note that "[t]his problem of poor activity of hop beta acids in fatty acid containing foods has prevented them [the hop beta acids] from being used commercially as natural antimicrobial agents for control of listeria or other gram positive pathogens" (page 2, lines 24 - 29). Therefore, even assuming arguendo, that Wilhoit and Millis et al. may be properly combined, that combination will nevertheless fail to teach that hop beta acids used alone may successfully protect meat from Listeria contamination. Accordingly, it is respectfully submitted that claims 1-10 are patentable over Wilhoit in view of Millis et al.

2. Wilhoit discloses an antimicrobial composition comprising a combination of (a) a Streptococcus-derived bacteriocin or a Pediococcus-derived bacteriocin or a synthetic equivalent; and (b) a chelating agent (lines 17-21 of column 4), even tough the use of bacteriocins alone is also claimed. This composition has unexpectedly good bactericidal properties against pathogenic bacteria such as Listeria monocytogenes (lines 21-23 of column 4 of Wilhoit) and may be applied, for example, to the inside of a cellulosic casing which may be stuffed with a food product such as a meat emulsion, for example, in order to contact the foodstuff with the agent (lines 23-32 of column 12).

Claim 1-10 of the present application differ from the method of Wilhoit in that the bactericidal agent is a hop-based component and not a bacteriocin or a combination of a bacteriocin and a chelating agent.

The substitution of bacteriocins (disclosed in Wilhoit) for hop beta acids (disclosed in Millis et al.) is not obvious since:

- Bacteriocins are of protein nature and hydrophilic, while hop beta acids and

hydrogenated hop beta acids are quite hydrophobic. This feature results in a low efficacy in high fat content food products. Therefore, it can not be expected that the substitution of bacteriocins for a hop beta acid leads will produce a similar effect.

- Size and molecular weight of both compounds are quite different as bacteriocins are polypeptides and hop beta acids are complex isoprenoids.
- Allergenicity and the possible resistance appearance, typical of bacteriocins, will not be so relevant for hop beta acids since their molecular weight is lower.
- The antibacterial spectrum of both are different
- Bacteriocins can be inactivated during the thermal treatment when cooking the meat product, while the hop beta acids retain their antibacterial activity during it.
- Prices and simplicity of purification are also quite different.

3. Millis et al. disclose a process comprising applying a composition containing 6 to 100 ppm of beta-acids as extracted from hops to a solid food product to incorporate from 6 to 50 ppm of beta-acids in said food product to prevent growth of Listeria in said food product. Among these solid foods which may be contaminated with Listeria as processed meats are mentioned (lines 26-29 of column 3 of Millis et al.), even though there is no example illustrating processed meats, and only the antibactericidal effect of the composition is showed in liquid cultures (Mueller Hinton broth and brain-hearth broth) (Examples 2-3).

Claims 1-10 of the present application thus differ from the method of Millis et al. in that the bactericidal agent is at least one hop-based component selected from a hop extract, a hydrogenated hop extract, hop alpha acids, hop beta acids, hydrogenated hop

acids and derivatives of hop acids or their resins.

The applicant considers that the present invention corresponds to an extension of the object of Millis et al., since Millis et al. mention the use of beta-acids and their derivatives, while the present invention considers the application of a series of compounds derived from hops, which also present antimicrobial activity (greater than that of beta acids) and are not referred to nor suggested in Millis et al.

These compounds derived from hops are specified in US Patent 5,455,038 to Barney (cited in paragraph [0021] of specification) in which the antimicrobial activity of hop derivatives, such as hexahydrocolupulone or tetrahydroisohumulone, is demonstrated, or in US Patent 6,326,185 (cited in paragraph [0022] of specification) in which tetrahydroisoalpha acids and also hexahydroalpha acids are used as antimicrobial agents in beer yeast.

4. Additionally, the claims of the present application differ from the method of Millis et al. in that the antibacterial composition of the present invention is applied to the internal surface of a cellulosic casing used to make sausages, and is not applied directly to the product or just tested in a liquid culture as in Millis et al.

In relation to the use of cellulosic casings, it would not have been obvious to apply the composition disclosed in Millis et al. to the cellulosic casings disclosed in Wilhoit since in the production of a cellulosic casing containing hop-based components the following aspects must be taken into account:

- The compatibility of the hop-based components with the cellulose material of casing and with the additives incorporated therein (oils or peeling agents, for example).

- The possible diffusion or immobilization of the components within the cellulosic casing matrix.

- The effect of the components on the pH of the cellulosic casing (with the risk of possible hydrolysis of the cellulosic chains when the pH obtained is not appropriate).

- The amount of the transferred components present in the inside of the cellulosic casing to the food product (kinetics of transference over time, percentage of effective transference of antimicrobial agents from the casing to the food).

Thus, there is no obvious reason to combine the teachings of Wilhoit and Millis et al. and thereby render the claims unobvious under 35 USC § 103.

5. Further, the use of a cellulosic casing presents several different characteristics compared to simply immersing the food product in an antimicrobial bath:

a) The antibacterial component should resist the cooking process since it is in contact with the food product and then is submitted to the same heat treatment processes (cooking, drying etc.) as the food product is.

b) The antibacterial component should be transferred from the casing to the food. In the case of the bath, this phenomenon of transfer from the bath to the food occurs easily and without impediments. In the case of a casing containing the antibacterial component, this should migrate from the casing to the product. Moreover, in the case of cellulosic casings, this migration is almost impeded for high molecular weight products (higher than 13,000 Dalton) and for hydrophobic compounds, which hardly diffuse through the hydrophilic cellulosic matrix. Therefore, this kind of compound cannot be used to impregnate the cellulosic casing in this antimicrobial application since, as they remain in

the cellulosic casing, the antimicrobial protection is only conferred to the casing (this is desired in some casings to discourage mould formation), but the protection is not conferred to the food inside the casing. If these compounds are to be used, they should be used to coat the interior surface of the casings, on the surface in direct contact with the food, to ensure that the casing does not impede transferring these antimicrobial compounds to the food.

c) The transference of the antibacterial component to the food presents certain special characteristics in the case of cellulosic casings. In the case of a food packaging that contains an antimicrobial agent, a continuous and sustained transfer of the antibacterial component to the food is preferable, in order to achieve a continuous microbial inhibition. In some cases the food packaging is in contact with the food to be protected throughout its entire useful life. In the case of a cellulosic casing, the contact is temporary, starting when the casing is filled with the meat paste until it is cooked (and optionally smoked) in this casing; after the cooking process, and when the surface layers of the sausage have formed a coagulated protein layer able to ensure the integrity of the sausage, the cellulosic casing is cut and removed and then the sausages are packed in packets of several units for sale to the consumer. In this case, transfer of the antimicrobial agent should take place in the short period of time during which the sausage and the cellulosic casing (which acts as a temporary mold during the cooking process) are in contact, transferring to the sausages the antimicrobial capacity against possible subsequent contamination, and not in a slow sustained mode as occurs for other food packaging.

d) The hydrophilic structure of the cellulosic casing, permeable to hydrophilic

compounds, should prevent the possible diffusion of the antimicrobial agent to outside the casing (which would result into a reduction of the antimicrobial activity transferred to the food).

e) The material of the casing should not interfere with the function of the casing, which must maintain its physical properties (stability, sausage diameter, stick rigidity, good peeling etc.). For example, plastic materials are considered to be essentially inert against food products and, hence, also against the antimicrobial components. In the case of cellulosic casings, which are sold in a highly compressed form as folded sticks, it is not easy to imagine how an antimicrobial component that exerts its inhibitory activity in a bath, has the same effect as when added to a cellulosic casing, since the possible interaction between both components must be taken into account. Hence, this interaction can cause the folds of the stick to adhere together, or can affect the diameter of the sausage, or its resistance to traction, making the functionality of the cellulosic casing non-viable. Similarly, the pH characteristics or the components themselves can break down the structure of the cellulosic casing (with the risk of possible hydrolysis of the cellulosic chains if the pH obtained is not appropriate) or the other sausage ingredients (such as ingredients to facilitate peeling which are also added to the sausage wall), interfering with the functionality of the casing.

Hence, the combination of, Casing + antimicrobial agent = antimicrobial casing + interaction means that the effect of an antimicrobial compound applied to the surface of the food product will not necessarily produce a useful antimicrobial casing, such as the cellulosic casing used in the said invention.

In the light of the above comments, it is believed that the claims of present application meets the requirements of nonobviousness, since the composition and the method of the present application does not appear evident from the combination of Wilhoit and Millis to a person of ordinary skilled in the art.

Accordingly, the application and claims are believed to be in condition for allowance, and favorable action is respectfully requested.

If any issues remain which may be resolved by telephonic communication, the Examiner is respectfully invited to contact the undersigned at the number below, if such will advance the application to allowance.

Respectfully submitted,

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